DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

November 12,2014

Ortho Specialties, Incorporated
C/O Ms. Paula Wendland
Regulatory Affairs Consultant
207 Pheasant Meadow Court
Gurnee, IL 60031

Re: K140807
Trade/Device Name: Composite Brackets
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: DYW
Dated: September 22, 2014
Received: October 1, 2014

Dear Ms. Wendland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 6.0 INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K140807

Device Name: _____ COMPOSITE BRACKETS _____

Indications for Use:

The Composite Brackets are intended for use as a clear, plastic bracket system to provide orthodontic movement of natural teeth.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Section 5.0 510 (k) Summary

Note: This summary is provided in accordance with 21CFR807.92(c).

510(k) Owners Name: Ortho Specialties, Inc.
Tim Allesee, President/Owner

Address: 3820 Ohio Ave. Suite 15
Saint Charles, IL 60174 USA

Contact Phone Number: 224-420-0125
Fax Number: 630-443-0224

Contact Person: Paula Wendland, Regulatory Affairs Consultant (Preparer)

Date 510(k) Summary was Prepared: March 22, 2014

Medical Device Name:

- Trade name – Composite Brackets
- Common name – Plastic Orthodontic Brackets
- Classification name –orthodontic plastic bracket (21CFR872.5470, Product Code DYW, Class II Device)

LEGALLY MARKETED DEVICES TO WHICH EQUIVALENCE IS CLAIMED (PREDICATE DEVICE) [807.92(a) (3)]:

- Elation MB ™ by Dentsply/GAC, Inc. K092030
- CDB Reflections Composite Bracket System, K973776

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5.1 DESCRIPTION OF THE APPLICANTS DEVICE:

Composite brackets provide a clear, aesthetic option for patients undergoing orthodontic treatment. The Composite Bracket system is designed to provide simple, aesthetic bonded brackets to correct minor to complicated mal-alignments in patients with permanent dentition (second molars) or mixed dentition using current orthodontic diagnosing techniques with orthodontic arch wires. The system consists of a series of clear, plastic brackets that conform to each tooth and its anatomy and adheres with a bracket base bearing a mechanical retention surface. They are provided with or without a metal archwire slot. Additional accessories to the brackets, depending on the dental professionals' technique, may include small hooks for the use of elastics and auxiliary arch wire tubes. Each bracket applies incremental, progressive force to reposition teeth to achieve ideal alignment, as prescribed by the treating dental practitioner. The composite brackets are bonded to the patient's teeth by traditional orthodontic direct and indirect bonding techniques using Orthodontic adhesives. These techniques are understood and documented in formal, orthodontic literature.
Removal method of the composite brackets at the conclusion of treatment is consistent with standard bracket removal methods reported in orthodontic literature and require no additional instructions. The removal method is identical to those required for the predicate device.

The Composite Brackets will be marketed in bulk (for up to 5 full arches) using a circular tray dispenser with identification key for each bracket type and tooth position. The Composite brackets are also available in a clear, plastic tray for a single patient arch.

5.2 INTENDED USE AND POPULATION:

The Composite Brackets are intended for use as a clear, plastic bracket system to provide orthodontic movement of natural teeth.

5.3 PREDICATE DEVICE:

Dentsply Elation MB bracket system, 510(k) submission (K092030) dated 7/24/2009 is similar in intended use and compositional technology compared to the Composite Brackets described in this submission for brackets with metal reinforced slots.

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CDB Reflections Composite bracket system, 510(k) submission (K973776), dated 11/21/1997 is similar in intended use compared to Composite Brackets described in this submission for brackets that do not contain metal reinforced slots.

5.4 TECHNOLOGICAL AND PERFORMANCE CHARACTERISTICS:

Performance Characteristics of COMPOSITE BRACKETS versus GAC Elation MB and CDB Reflections:

Property	**Composite Brackets**	**GAC Elation MB**	**CDB Reflections**
Intended Use	**Plastic, Orthodontic Bracket with or without metal reinforced slots for alignment of teeth**	**Plastic, Orthodontic Bracket with metal reinforced slots for alignment of teeth**	**Plastic, Orthodontic Bracket without metal reinforced slots for alignment of teeth**
Composition	**Polycarbonate**	**Polycarbonate**	**Polycarbonate**
Aesthetic Features	**Clear (translucent) bracket system**	**Clear (translucent) Bracket System with reinforced metal slots**	**Clear (translucent) bracket system**
Mode of Use	**Archwire implementation by dental professional's technique**	**Archwire implementation by dental professional's technique**	**Archwire implementation by dental professional's technique**
Physical Properties	**Mechanical Retention base eliminating need for plastic condition pre-treatment Non-Toxic ink on brackets for identification**	**Mechanical Retention base eliminating need for plastic condition pre-treatment Non-Toxic ink on brackets for identification**	**Base requires Plastic Conditioner prior to bonding with an orthodontic adhesive. Non-Toxic ink on brackets for identification**
Application	**Bonded**	**Bonded**	**Bonded**
Manufacturing Method	**Molded, thermo-formed**	**Molded, thermo-formed**	**Molded, thermo-formed**

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5.5 Summary:

Composite Brackets of thermoplastic polycarbonate composition have been well documented in literature (Pithon M., Lacerda dos Santos R., Martins F., Ruellas A., Nojima L., Nojima M., Romanos, M. (2009) Cytotoxicity of Polycarbonate Orthodontic Brackets, Brazilian Journal of Oral Science, April/June 2009 - Volume 8, Number 2).

Cytotoxicity testing was conducted using the ISO 10993-5 Elution Method. The Composite Orthodontic Brackets were evaluated for potential cytotoxic effects using an in vitro mammalian cell culture test following the guidelines of ISO10993-5, Biological evaluation of medical device - Part 5: Tests for in vitro cytotoxicity. The Composite Orthodontic Brackets showed no evidence of causing cell lysis or toxicity and met the requirements of the test with a grade of less than grade 2 (Mild reactivity).

Oral Mucosal irritation testing was conducted using ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. The Composite Orthodontic Brackets were evaluated for potential to cause oral mucosal irritation in hamsters. The Composite Orthodontic Brackets were considered a nonirritant to the oral mucosa of the hamster.

Based on characteristics of intended use, application, composition, aesthetics and physical property testing showing similar shear bond and compressive strength, the Composite brackets are substantially equivalent to the predicate devices (Dentsply Elation MB and CDB Reflections Composite bracket systems).

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